BK030035

Traditional 510(k)
bioMérieux, Inc.
BacT/ALERT BPA Culture Bottle
Glass Culture Bottle to Plastic Culture Bottle

510(k) Summary

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name:	bioMérieux, Inc
Submitter's Address:	100 Rodolphe Street, Durham, North Carolina 27712
Submitter's Telephone:	(919) 620-2682
Submitter's Contact:	Troy C. Quander T.Q.
Date 510(k) Summary Prepared:	May 30, 2003

The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

Trade or Proprietary Name: BacT/ALERT BPA Culture Bottle

Common or Usual Name: BacT/ALERT BPA Culture Bottle

Classification Name: Microbial Growth Monitor

An identification of the legally marketed device to which the submitter claims substantial equivalence;

Device Equivalent to: BacT/Alert SA Glass Culture Bottle

(a)(4) **A description of the device.**

Device Description: The BacT/ALERT BPA Plastic Culture Bottle was developed for the same intended use as the current BacT/ALERT SA Glass Culture Bottle, but specifically designed to be used for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. The BacT/ALERT BPA Culture Bottles support the growth of aerobic microorganisms (bacteria and fungi). An inoculated bottle is placed into the BacT/ALERT Microbial Detection Instruments where it is incubated and continuously monitored for the presence of microorganisms that will grow in the BacT/ALERT BPA Culture Bottle.

A statement of the intended use of the device.

Device Intended Use: BacT/ALERT BPA Culture Bottles are used with the BacT/ALERT Microbial Detection System for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. BacT/ALERT BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).

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(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**

The BacT/ALERT BPA Plastic Culture Bottle utilizes the same detection technology as the BacT/ALERT SA Glass Culture Bottle. The similarities and/or differences with marketed device are listed in Table (a) (6) 1.

TABLE (a)(6).1

FEATURES	BACT/ALERT BPA PLASTIC CULTURE BOTTLE	BACT/ALERT SA GLASS CULTURE BOTTLE (BK020023)
Intended Use	BacT/ALERT BPA Culture Bottles are used with the BacT/ALERT Microbial Detection System for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. BacT/ALERT BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).	The BacT/ALERT SA Culture Bottles are used with the BacT/ALERT Microbial Detection System in qualitative procedures for the recovery and detection of aerobic microorganisms (bacteria and fungi) from blood and other normally sterile body fluids. BacT/ALERT SA Culture Bottles may also be used for quality control testing of leukocyte reduced platelet (LRAP) units
Culture Bottle Material	Plastic	Glass
Product Code	MZC	MZC
Technology	Reflectance	Reflectance
Color change based on CO_2 production	YES	YES
Sensor	Emulsion	Emulsion
Indicator material	Xylenol Blue in Silicone Emulsion	Xylenol Blue in Silicone Emulsion
Growth of microorganisms	Same	Same
Instrument Used	BacT/ALERT Microbial Detection Systems	BacT/ALERT Microbial Detection Systems
Sample Source	LRAP	LRAP
Target Population	Adult	Adult
Media Formulation	Same	Same

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(b)(1) **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Testing was performed to establish the performance characteristics of the new device including:

Seeded studies were performed on 9 organisms diluted in platelets and inoculated into the BacT/ALERT BPA Plastic Culture bottle and the BacT/ALERT SA Glass Culture bottle.

(b)(2) **A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Not Applicable

(b)(3) **The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

The BacT/ALERT BPA Plastic Culture Bottle was substantially equivalent to the BacT/ALERT SA Glass Culture Bottle based on recovery of low levels of the 9 microorganisms included in the study. Detection times were equivalent in both bottles.